

**Translation**


**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

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PCT/DE2003/002455



Applicant's or agent's file reference P01681WO	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/DE2003/002455	International filing date (day/month/year) 22 July 2003 (22.07.2003)	Priority date (day/month/year) 22 July 2002 (22.07.2002)
International Patent Classification (IPC) or national classification and IPC A61M 1/16		
Applicant REUL, Helmut		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>12</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>21</u> sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input checked="" type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 03 February 2004 (03.02.2004)	Date of completion of this report 07 October 2004 (07.10.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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## I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

☐ the international application as originally filed.

☒ the description, pages 1-22, as originally filed,  
 pages \_\_\_\_\_, filed with the demand,  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

☒ the claims, Nos. \_\_\_\_\_, as originally filed,  
 Nos. \_\_\_\_\_, as amended under Article 19,  
 Nos. \_\_\_\_\_, filed with the demand,  
 Nos. 1-88, filed with the letter of 28 July 2004 (28.07.2004),  
 Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

☒ the drawings, sheets/fig 1-11, as originally filed,  
 sheets/fig \_\_\_\_\_, filed with the demand,  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

2. The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/fig \_\_\_\_\_

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

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## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 19, 20, 24, 25, 34, 35, 39, 40, 49, 50, 54, 55, 64, 65, 69, 70, 80, 81, 84, 85

because:

☐ the said international application, or the said claims Nos. \_\_\_\_\_  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 19, 20, 34, 35, 49, 50, 64, 65, 80, 81  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 24, 25, 39, 40, 54, 55, 69, 70, 84, 85.

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## IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-18, 21-23, 26-33, 36-38, 41-48, 51-53, 56-63, 66-68, 71-79, 82, 83, 86-88 .

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOXES III.1 and IV.3**Box III.1**

**Non-establishment of opinion with regard to novelty,  
inventive step and industrial applicability**

The term "moment equilibrium" used in claims 19, 20, 34, 35, 49, 50, 64, 65, 80 and 81 is unclear and leaves the reader uncertain about the meaning of the technical feature in question. As a result, the subject matter of these claims is not clearly defined (PCT Article 6).

**BOX IV.3**

**Lack of unity of invention**

The examiner has determined that the international application contains multiple (groups of) inventions which are not linked by a single general inventive concept (PCT Rule 13.1), as follows:

- I. Claims 1-9
- II. Claims 10-18, 21-23, 26-33, 36-38, 41-48, 51-53,  
56-63, 66-68, 71-79, 82, 83
- III. Claims 86-88

The reasons therefor are as follows:

The three independent claims 1, 10 and 86 of the three inventions relate to an intravenous oxygenator with a fibre bundle whose fibres are connected by means of a first and a second connections to a gas duct system (gas supply and discharge), so that oxygen and carbon dioxide can flow through the fibres from the first connections to

## Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOXES III.1 and IV.3

the second connections.

Moreover, claim 1 contains the feature that the fibre bundle is twisted about a longitudinal axis of the oxygenator in that the first connections are rotated relative to the second connections of the fibres and in that an adjacent fibre bundle arranged in series is twisted in the same direction as the first fibre bundle.

As indicated in the description of the present application (see page 3, lines 13-20), the twisting of the fibre bundle causes the fibres to be more densely packed and creates a plurality of elongated, flat slots between the fibres which act as blood flow channels. This is supposed to improve gas exchange.

According to claim 10, the oxygenator further contains the following features:

The connections are linked to a first and to a second fibre holders and can be displaced along a longitudinal axis of the oxygenator. The fibre holders are sliding elements and can be rotated relative to one another about the longitudinal axis of the oxygenator. The fibre holders are optionally also movable along said axis.

This causes the fibres to be impinged by a flow mainly in the perpendicular direction, in that the fibres bulge outwards when the connections are pushed towards each other (see page 5, lines 13-32 of the description, figure 3).

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOXES III.1 and IV.3

It is pointed out that according to claim 10 the fibres need not be twisted in the state of utilisation. Only the fibre holders must be mounted so as to rotate relative to one another.

In addition to the features which are common to all three claims, claim 86 includes the following features:

The oxygenator contains at least one other fibre bundle and a mixing channel through which a gas can flow between different connections.

This mixing channel is supposed to generate a parallel flow through the fibres (see claim 86).

According to claim 86, the fibre bundles need not be twisted and the fibre holders need not be mounted in a rotatable or longitudinally movable manner.

The only connection between the subjects of claims 1, 10 and 86 is that all three claims relate to an intravenous oxygenator having a fibre bundle with two connections. These common features help to determine the preamble of the inventions, which is known from the prior art. However, these features do not constitute "special technical features" which determine the contribution of the invention over the prior art within the meaning of PCT Rule 13.2.

Th distinguishing features of claims 1, 10 and 86 relate,



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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOXES III.1 and IV.3

on the contrary, to different technical concepts which are not related to one another and which have different, independent technical effects.

Consequently, no common inventive concept linking the inventions can be determined and claims 1, 10 and 86 lack unity of invention *a priori*.

In addition, it is pointed out that the different independent claims of the second group of inventions (claims 10, 26, 41, 56 and 71) also lack unity of invention.



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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	1-18, 21-23, 26-33, 36-38, 41-48, 51-53, 56-63, 66-68, 71-79, 82, 83, 88	YES
	Claims	86, 87	NO
Inventive step (IS)	Claims	1-18, 21-23, 26-33, 36-38, 41-48, 51-53, 56-63, 66-68, 71-79, 82, 83	YES
	Claims	88	NO
Industrial applicability (IA)	Claims	1-18, 21-23, 26-33, 36-38, 41-48, 51-53, 56-63, 66-68, 71-79, 82, 83, 86-88	YES
	Claims		NO

## 2. Citations and explanations

1. This report makes reference to the following documents:

D1: EP-A-0 631 790 (ELECTROMEDICS INC; HATTLER  
BRACK G (US))

D7: US-A-5 037 383 (VASLEF STEVEN N ET AL)

**First invention (claims 1-10)**

Document D1 is regarded as the prior art closest to the subject matter of claim 1 and discloses an intravenous oxygenator for enriching blood with oxygen according to the preamble of claim 1.

The subject matter of claim 1 differs from the known oxygenator in that an additional fibre bundle is provided in series with the first fibre bundle, along the oxygenator, and twisted in the same direction as the first fibre bundle.

The subject matter of claim 1 is therefore novel (PCT Article 33(2)).

The present invention can be considered to address the

problem of generating a more homogeneous flow.

The solution to this problem, as proposed in claim 1 of the present application, involves an inventive step (PCT Article 33(3)) for the following reasons:

None of the search report citations discloses a constellation of two or more fibre bundles arranged in series and twisted in the same direction. The advantage of this arrangement is that a specially good flow is generated along the fibres over a long blood flow section, without rendering the individual fibres too unstable or too long.

Claims 2-9 are dependent on claim 1 and therefore also meet the PCT novelty and inventive step requirements.

**Second invention (claims 10-18, 21-23, 26-33, 36-38, 41-48, 51-53, 56-63, 66-68, 71-79, 82, 83)**

**Claims 10-18, 21-23**

PCT Article 6

Contrary to PCT Article 6, claim 10 is not supported by the description because its scope goes beyond the scope justified by the description and the drawings, for the following reasons:

The description (see page 8, last paragraph) indicates that the fibre holders are located inside the fibre bundle and are designed as sliding elements which slide on a central catheter. The description therefore does not disclose an embodiment in which the fibre holders would be arranged as sliding elements outside the fibre bundle, as proposed by claim 11. Moreover, it would be unclear on

what the fibre holders would slide in such an embodiment.

Consequently, it is assumed when assessing novelty and inventive step that the fibre holders are located inside the fibre bundle and that a central catheter is provided and is surrounded by the fibre holders as sliding elements, so that they can be moved along the longitudinal axis of the oxygenator. Moreover, the expression "in particular" is construed to mean "and".

PCT Article 33(2) and 33(3)

Document D7 is regarded as the prior art closest to the subject matter of claim 10 and discloses an intravenous oxygenator according to the preamble of claim 10.

The subject matter of claim 10 differs (in its clarified definition) from the known oxygenator in that the fibre holders are sliding elements which are arranged inside the fibre bundle, can be rotated relative to one another about the longitudinal axis of the oxygenator and relative to the central catheter, and can be moved along said axis.

The subject matter of claim 1 is therefore novel (PCT Article 33(2)).

The present invention can be considered to address the problem of preventing fibre orientation from being affected by the fibre holders.

The solution to this problem, as proposed in claim 10 of the present application, involves an inventive step (PCT Article 33(3)) because the prior art neither describes nor suggests this arrangement of the fibre holders, which ensures a specially good twistability of the fibre holders.

Claims 11-18 and 21-23 are dependent on claim 10 and therefore also meet the PCT novelty and inventive step requirements.

**Claims 26-33, 36-38**

Document D7 is regarded as the prior art closest to the subject matter of claim 26 and discloses an intravenous oxygenator according to the preamble of claim 26.

The subject matter of claim 26 differs from the known oxygenator by a first carrier on the first fibre holder and a second carrier on the second fibre holder, the carriers being oriented towards one another. When the two fibre holders are pressed against each other, the first fibre holder can twist relative to the second fibre holder at least in one direction of rotation only up to a limit without causing the second fibre holder to twist.

The subject matter of claim 26 is therefore novel (PCT Article 33(2)).

The present invention can be considered to address the problem of permitting a predetermined twist to be adjusted.

The solution to this problem, as proposed in claim 26 of the present application, involves an inventive step (PCT Article 33(3)) because the prior art neither shows nor suggests fibre holders with carriers, as defined in claim 26. The advantage of this arrangement is that a predetermined twist of the oxygenator can be blindly adjusted.

Claims 27-33 and 36-38 are dependent on claim 26 and therefore also meet the PCT novelty and inventive step requirements.

**Claims 41-48, 51-53**

Document D7 is regarded as the prior art closest to the subject matter of claim 41 and discloses an intravenous oxygenator according to the preamble of claim 41.

The subject matter of claim 41 differs from the known oxygenator by a stop on the fibre holders.

The subject matter of claim 41 is therefore novel (PCT Article 33(2)).

The present invention can be considered to address the problem of limiting the displacement of the connections in the axial direction.

The solution to this problem, as proposed in claim 41 of the present application, involves an inventive step (PCT Article 33(3)) because the prior art neither shows nor suggests fibre holders with a stop. The advantage of this arrangement is that it prevents the fibres from buckling when they are spread.

Claims 42-48 and 51-53 are dependent on claim 41 and therefore also meet the PCT novelty and inventive step requirements.

**Claims 56-63, 66-68**

Document D7 is regarded as the prior art closest to the subject matter of claim 56 and discloses an intravenous

oxygenator according to the preamble of claim 56.

The subject matter of claim 56 differs from the known oxygenator by a spiral guidance of the fibre holders along the longitudinal axis of the oxygenator.

The subject matter of claim 56 is therefore novel (PCT Article 33(2)).

The present invention can be considered to address the problem of permitting the fibre bundle to be twisted in an easy and controllable manner.

The solution to this problem, as proposed in claim 56 of the present application, involves an inventive step (PCT Article 33(3)) because the prior art neither shows nor suggests a spiral guidance of the fibre holders.

Claims 57-63 and 66-68 are dependent on claim 56 and therefore also meet the PCT novelty and inventive step requirements.

#### **Claims 71-79, 82-83**

Document D7 is regarded as the prior art closest to the subject matter of claim 71 and discloses an intravenous oxygenator according to the preamble of claim 71.

The subject matter of claim 71 differs from the known oxygenator by a radially deformable housing with an impervious sheath.

The subject matter of claim 71 is therefore novel (PCT Article 33(2)).



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The present invention can be considered to address the problem of permitting the oxygenator to be precisely delimited.

The solution to this problem, as proposed in claim 71 of the present application, involves an inventive step (PCT Article 33(3)) because the prior art neither shows nor suggests an oxygenator with a radially deformable housing and an impervious sheath.

Claims 72-79 and 82-83 are dependent on claim 71 and therefore also meet the PCT novelty and inventive step requirements.

## **Third invention (claims 86-88)**

### PCT Article 6

Claims 86-87 do not meet the requirements of PCT Article 6 because the subject matter for which protection is sought is not clearly defined. An attempt is made in the characterising parts of both claims to define the subject matter in terms of the result to be achieved, namely "generating a flow parallel to the flow through the fibres" (claim 86) and "achieving a volumetric flow ratio of at least 4:1" (claim 87).

However, this only indicates the problem addressed without defining the technical features necessary to achieve this result.

Moreover, it is unclear what technical features are meant by the functional definition "mixing channel".

### PCT Article 33(2) and 33(3)

Document D7 (see figure 1) describes an intravenous



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oxygenator with a ring-shaped channel through which a gas can flow. Regardless of the foregoing objection on the grounds of lack of clarity, the subject matter of claims 86 and 87 is thus not novel.

The additional feature of claim 88, according to which the ring-shaped channel is located between a catheter with a single lumen and the fibres, cannot substantiate an inventive step.

**Further observation on all the inventions**

It is pointed out that the expressions "preferably", "in particular" and "specially preferred" used in some of the claims do not restrict the scope of protection, that is the features that follow these expressions are considered entirely optional.